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TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

Bret A. Ferree

For: **METHODS AND APPARATUS FOR TREATING DISC HERNIATION AND PREVENTING THE EXTRUSION OF INTERBODY BONE GRAFT**

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EL073516081US**
- ☒ **Thirteen (13)** sheets of drawings.
- ☐ A certified copy of a _____ application.
- ☒ Declaration ☒ Signed. ☐ Unsigned.
- ☒ Power of Attorney
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- ☐ Preliminary Amendment
- ☒ **One** Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
- ☐ Other:

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For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	18	- 20 =	0	x \$9.00	\$0.00
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Dated: **August 14, 2000**

Signature

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cc:

As the below named inventor, I hereby declare my residence, post office address and citizenship are as stated below next to my name; and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

the specification of which

- ☒ is attached hereto.
- ☐ was filed on _____ as ☐ Serial No. 0 / _____
or ☐ Express Mail No., as *Serial No. not yet known* _____
_____ and was amended on _____ (*if applicable*).
- ☐ was described and claimed in PCT International Application No. _____
_____ filed on _____ and as amended under PCT
Article 19 on _____ (*if any*).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge to the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, §1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

Priority Claimed

PCT/US00/14708	PCT	30 May 2000
(Number)	(Country)	(Day/month/year filed)

Yes	No
[X]	[]

(Number)	(Country)	(Day/month/year filed)
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[] []

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(App. Serial No.)	(Filing date)	(Status) (patented, pending, abandoned)
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I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

FILING DATE

August 13, 1999

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon.

Full name of sole inventor BRETT A. FERREE

Inventor's signature 

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METHODS AND APPARATUS FOR TREATING DISC HERNIATION AND PREVENTING THE EXTRUSION OF INTERBODY BONE GRAFT

Reference to Related Applications

This application claims priority of International Patent Application Serial No. PCT/US00/14708, filed May 30, 2000, which claims priority of U.S. Patent Application Serial No. 09/322,516, filed May 28, 1999, and U.S. Provisional Patent Application Serial
5 No. 60/148,913, filed August 13, 1999, the entire contents of each application being incorporated herein by reference.

Field of the Invention

This invention relates generally to the prosthetic appliances and, in particular, to devices for occluding intervertebral disc defects and instrumentation associated with
10 introducing the such devices.

Background of the Invention

Several hundred thousand patients undergo disc operations each year. Approximately five percent of these patients will suffer recurrent disc herniation, which results from a void or defect which remains in the outer layer (annulus fibrosis) of the disc
15 after surgery involving partial discectomy.

Reference is made to Figure 1A, which illustrates a normal disc as viewed from the feet of a patient up toward the head. The nucleus pulposus 102 is entirely surrounded by the annulus fibrosis 104 in the case of healthy anatomy. Also shown in this cross section is the

relative location of the nerves 106. Figure 1B illustrates the case of the herniated disc, wherein a portion of the nucleus pulposus has ruptured through a defect in the annulus fibrosis, resulting in a pinched nerve 110. This results in pain and further complications, in many cases.

5 Figure 1C illustrates the post-operative anatomy following partial discectomy, wherein a space 120 remains adjacent a hole or defect in the annulus fibrosis following removal of the disc material. The hole 122 acts as a pathway for additional material to protrude into the nerve, resulting in the recurrence of the herniation. Since thousands of patients each year require surgery to treat this condition, with substantial implications in
10 terms of the cost of medical treatment and human suffering, any solution to this problem would welcomed by the medical community.

Summary of the Invention

The subject invention resides in methods and apparatus for treating disc herniation, which may be defined as the escape of nucleus pulposus through a void or defect in the
15 annulus fibrosis of a spinal disc situated between upper and lower vertebra. In addition to preventing the release of natural disc materials, the invention may also be used to retain bone graft for fusion, therapeutic and artificial disc replacement materials. The invention is particularly well suited to the minimization and prevention of recurrent disc herniation, in which case the defect is a hole or void which remains in the annulus fibrosis following disc
20 operations involving partial discectomy.

In broad, general terms, to correct defects of this type, the invention provides a

conformable device which assumes a first shape associated with insertion and a second shape or expanded shape to occlude the defect. The device may take different forms according to the invention, including solidifying gels or other liquids or semi-liquids, patches sized to cover the defect, or plugs adapted to fill the defect.

5 The device is preferably collapsible into some form for the purposes of insertion, thereby minimizing the size of the requisite incision while avoiding delicate surrounding nerves. Such a configuration also permits the use of instrumentation to install the device, including, for example, a hollow tube and a push rod to expel the device or liquefied material out of the sheath for use in occluding the disc defect.

10 A device according to the invention may further include one or more anchors to assist in permanently affixing the device with respect to the defect. For example, in the embodiment of a mesh screen, the anchors may assume the form of peripheral hooks configured to engage with the vertebra on either side of the disc. The invention further contemplates a distracting tool used to force the anchors into the vertebra. Such a tool would
15 preferably feature a distal head portion conformal to the expanded shape of the device, enabling the surgeon to exert force on the overall structure, thereby setting the anchors.

Brief Description of the Drawings

FIGURE 1A is a cross section of a human disc exhibiting normal anatomy;

FIGURE 1B is a cross section used to illustrate a disc herniation;

20 FIGURE 1C is a drawing of a disc following a partial discectomy, showing how a space or void remains in the annulus fibrosis;

FIGURE 2 is a drawing which illustrates a preferred embodiment of the invention in the form of a flexible stent used to occlude a defect in the annulus fibrosis to minimize recurrent disc herniation;

FIGURE 3A is a drawing of an applicator used to insert the flexible mesh stent
5 embodiment of Figure 2;

FIGURE 3B shows the applicator of Figure 3A with the stent partially expelled;

Figure 3C illustrates a fully expanded shape assumed by the device of Figure 2 following removal of the insertion tool;

FIGURE 4A illustrates the addition of optional peripheral anchors around the stent in
10 the Figure 4 to assist in fixation;

FIGURE 4B is an end view of the device of Figure 4A including the peripheral anchors;

FIGURE 5 is a side-view drawing of the device of Figures 4A and 4B anchored into upper and lower vertebra bounding the herniated disc;

FIGURE 6A illustrates an optional distraction tool used to set the anchors of the
15 device of Figures 4 and 5 into the vertebra;

FIGURE 6B shows how the distracting tool would be inserted into the device to effectuate distraction;

FIGURE 7A is a side-view drawing in partial cross-section illustrating the way in
20 which notches may be made to adjoining vertebra to receive a device according to the invention;

FIGURE 7B is a drawing of a tool which may be used to form the notches depicted in

Figure 7A;

FIGURE 7C illustrates the way in which a flexible body may be retained by the notches described with respect to Figures 7A and 7B;

FIGURE 8 illustrates an alternative orientation of a flexible body having a convex
5 surface facing outwardly with respect to the wall of the disc being repaired;

FIGURE 9A illustrates how the device according to the invention may be fixed with anchors that penetrate through the disc to be captured at the outer wall thereof;

FIGURE 9B illustrates an alternative use of anchors which remain within the body of the disc material and do not penetrate its outer wall;

10 FIGURE 9C illustrates an alternative method of fixation, wherein bone anchors are introduced into the vertebrae on either side of the disc in need of repair, as opposed to anchors deployed within or through the disc itself;

FIGURE 10A illustrates an alternative device according to the invention in the form of a resilient plug;

15 FIGURE 11A illustrates an alternative embodiment of the invention wherein a coiled wire is used to occlude a disc defect;

FIGURE 11B is a side-view representation of the coiled wire of Figure 11A;

FIGURE 11C illustrates how a wire with a coiled memory shape may be straightened and introduced using a plunger-type instrument;

20 FIGURE 12 illustrates yet a different alternative embodiment of the invention wherein a material in liquid or gel form may be introduced into a defect, after which it hardens or solidifies to prevent further rupturing;

FIGURE 13A illustrates yet a further alternative embodiment of the invention, in the form of a stent having a plurality of leaves;

FIGURE 13B illustrates the alternative of Figure 13A, wherein the leaves assume a second shape associated with defect occlusion, preferably through memory affect;

5 FIGURE 14A illustrates an aspect of the invention wherein a conformable device is suspended within a gel or other resilient material for defect occlusion;

FIGURE 14B is a side-view drawing of the embodiment of Figure 14A;

FIGURES 15A-15E are drawings which show various different alternative embodiments according to the invention wherein a patch is used inside and/or outside of a
10 void in need of occlusion;

FIGURE 16A is a top-view, cross-sectional drawing of a version of the invention utilizing posts or darts and sutures;

FIGURE 16B is a side-view drawing of the embodiment of Figure 16A;

FIGURE 17A shows how posts or darts may be criss-crossed to form a barrier;

15 FIGURE 17B is a side-view drawing of the configuration of Figure 17A;

FIGURE 18A is a side-view drawing of a barbed post that may be used for occlusion according to the invention;

FIGURE 18B is an on-access view of the barbed post;

FIGURE 18C illustrates how a single larger barbed post may be used for defect
20 occlusion;

FIGURE 18D illustrates how the barbed post of Figures 18A and 18B may be used in plural fashion to occlude a defect;

FIGURE 19A is a drawing which shows how shaped pieces may be inserted to close off an opening;

FIGURE 19B continues the progression of Figure 19A, with the pieces being pulled together;

5 FIGURE 19C illustrates the pieces of Figures 19A and 19B in a snapped-together configuration;

FIGURES 20A-20E are a progression of drawings which show how a shaped body may be held into place with one or more wires to block off a defect;

10 FIGURES 21A-21C illustrate how wires may be used in conjunction with snap-on beads to occlude a defect;

FIGURE 22A illustrates the insertion of members adapted to receive a dam component;

FIGURE 22B illustrates the dam of Figure 22A locked into position;

15 FIGURE 23A illustrates one form of defect block that accommodates compression and distraction;

FIGURE 23B shows the device of Figure 23A in compression;

FIGURE 23C shows the device of Figure 23A in distraction;

FIGURE 23D illustrates the way in which the device of Figures 23A-23C, and other embodiments, may be tacked into place with respect to upper and lower vertebrae;

20 FIGURE 24A is a drawing which shows an alternative device that adjusts for compression and distraction, in the form of a resilient dam,

FIGURE 24B shows the resilient dam in compression;

FIGURE 24C shows the resilient dam in distraction;

FIGURE 25 illustrates a different configuration for the insertion of a resilient dam according to the invention;

FIGURE 26 illustrates an alternative Z-shaped dam of resilient material;

5 FIGURE 27A illustrates the use of interlocking fingers that permit compression and distraction while occluding a defect;

FIGURE 27B is a side-view drawing in cross-section of the configuration of Figure 27;

FIGURE 28A illustrates an alternative interlocking finger configuration, and the way
10 in which such members are preferably installed;

FIGURE 28B shows how the first of the multiple members of Figure 28A is installed;

FIGURE 29A is a side-view drawing of a non-contained silicon blocking member prior to distraction;

FIGURE 29B illustrates the way in which the device of Figure 29A deforms upon
15 distraction;

FIGURE 30A is a side-view drawing in cross-section illustrating a contained silicon structure prior to distraction;

FIGURE 30B illustrates how the contained silicon structure of Figure 30A remains essentially the same in shape upon distraction;

20 FIGURE 31A illustrates the use of threaded metal plug with particular applicability to bone graft retention;

FIGURE 31B illustrates a rigid plug with ridges enabling it to be impacted into place;

FIGURE 31C shows the use of asymmetric ridges to resist posterior migration;

FIGURE 31D shows how teeth, screw threads or ridges on certain plug embodiments would extend at least partially into the adjacent vertebra for secure purchase; and

FIGURE 32 illustrates bilateral plug positioning according to the invention.

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Detailed Description of the Invention

Having discussed the problems associated with post-operative partial discectomy with respect to Figures 1A-1C, reference will now be made to Figure 2, which illustrates a preferred embodiment of the invention, wherein a device in the form of a stent 202 is used to occlude a defect 204 in a human disc, as shown. In this preferred embodiment, the device is
10 composed of a flexible material, which may be cloth, polymeric or metallic. For reasons discussed below, a titanium mesh screen is preferred with respect to this embodiment of the invention.

A flexible device is also preferred because the surgeon is presented with a very small working area. The incision through the skin is typically on the order of 1 to 1.5 inches in
15 length, and the space at the disc level is approximately 1 centimeter on the side. As a consequence, the inventive device and the tools associated with insertion and fixation described below must be sufficiently narrow to fit within these confines.

As shown in Figures 3A-3C, a flexible screen enables the device to be collapsed into an elongated form 302, which, in turn, facilitates introduction into a sheath 304 associated
20 with insertion. A push rod 306 may then be introduced into the other end of the sheath 304, and either the sheath pulled backwardly or the push rod pushed forwardly, or both, resulting

in the shape shown in Figure 3C, now suitable for implantation.

To further assist in fixation with respect to the surrounding physiology, anchors 402 may be provided around a peripheral edge of the device, as shown in Figure 4A. Figure 4B shows an end view of the device of Figure 4A, and Figure 5 illustrates the device with
5 anchors generally at 500, being fixed relative to a defective disc 504 bounded by upper and lower vertebrae at 502. It will be apparent to those of skill that each of the devices disclosed herein may be made in different sizes, having varying peripheral dimensions, for example, to match differently sized defects.

Figure 6A and 6B illustrate how a distracting tool 602 may be used to force the
10 anchors into the vertebrae. That is, having introduced the device into the approximate area, the tool 602, having a forward shape corresponding to that of the expanded mesh shape, may be introduced therein, as shown in Figure 6B. With force being applied to the tool 602, the anchors may be permanently set into the surrounding bone/ tissue.

Figure 7A illustrates an alternative approach to fixation, wherein one or more
15 notches 700 may be made into the upper and lower vertebra, preferably through the use of an air-operated drill 704 shown in Figure 7B, having a cutting wheel 702 adapted for such a purpose. Figure 7C illustrates the way in which a flexible body 708 may be retained by the notches 700 described with respect to Figures 7A and 7B. Figure 8 illustrates an alternative orientation of a flexible body having a convex surface facing outwardly with respect to the
20 wall of the disc being repaired.

Figure 9A illustrates a further alternative associated with fixation wherein anchors 902 which penetrate the outer wall of the disc 905 are used to hold a flexible repair device

900 in place as shown. Figure 9B shows yet a further alternative fixation modality, wherein disc anchors 906, which do not penetrate the outer wall of the disc, but, rather remain there within, are used to hold the device 904 in place.

Figure 9C illustrates yet a further alternative mode of fixation, wherein anchors 908
5 are used to hold the device to upper and lower vertebra, as opposed to the anchors of Figures 9A and 9B, which are used with respect to the disc. Regardless of whether fixation takes place within the vertebra or within the disc, it will be noted that according to the preferred embodiment of the invention, both the device used to occlude the defect and the fixation means are sufficiently flexible that the defect remains occluded with movement of the spine,
10 that is, with the patient leaning forwardly and backwardly which will tend to change the spacing between the upper and lower vertebra.

Figure 10 illustrates yet a different embodiment of the invention wherein, as opposed to a piece of flexible material or mesh, a resilient plug 1002 is instead utilized to occlude the disc defect. As in the case of the flexible sheath-like embodiments described above, such
15 plugs are preferably offered in different sizes to correlate with differently sized defects.

In terms of a preferred material, a device according to the invention will therefore remain sufficiently flexible during movement while being capable of exerting continuous outward forces and withstanding repetitive compression and distraction of millions of cycles. The device would, therefore, preferably be made of a material that has these characteristics,
20 while, additionally being radio-opaque for X-ray imaging, without producing too many unwanted artifacts in magnetic resonance imaging. A wire mesh of titanium is therefore preferable, since this has the proper X-ray/MRI characteristics while exhibiting the requisite

flexibility for the cyclic flexion and extension. With respect to the embodiment of Figure 10, a resilient, rubber-like material may be used to occlude the defect as shown in the drawing from a side-view perspective.

The invention is not limited in the sense that any conformable device may be used
5 with a first shape permitting the device to be introduced into the defective area and a second shape wherein the device includes a defect. As shown in Figures 11A-11C, for example, a wire 1102 having a "memory effect" may be used, preferably having a final diameter which is larger than void 1104. Figure 11B shows the coil 1102 in cross-section between upper and lower vertebra. Preferably, this embodiment would use a metal wire that may be
10 straightened, but retain the memory of its coiled shape. As such, the apparatus of Figure 11C may be used to introduce the wire in straightened form 1108 with a plunger 1110, such that as the wire exits at 1106, it returns to its memorized state of a coil (or alternative second shape operative to include the defect).

As yet a different alternative mode of introduction, a material may be injected into
15 the disc in liquid form, then allowed to hardened into a size sufficient to occlude the annular hole. As shown in Figure 12, material 1202 may be injected into the void of the disc space using a plunger 1204 inserted into a tube 1206. Upon introduction in this manner, the liquid would then solidify, forming a resilient plug.

Various materials may be utilized for this purpose, including various polymers which
20 are caused to solidify by various means, including thermal or optical activation, or chemical reaction as part of multi-part compounds. A preferred material with respect to this embodiment would be a hydrogel. Hydrogels may be placed into the disc in a dehydrated

state, and, once inside the disc, they imbibe water. After hydration, hydrogels have the same biomechanical properties as a natural nucleus and, in addition, as the hydrogels swell, they become too large to extrude back through the annular window. Patent Nos. 5,047,055 and 5,192,326 provide a listing of hydrogels, certain of which are applicable to this invention.

5 An elastomer may be used as an alternative to a hydrogel or other material. A number of elastomers may be suited to the invention, including a silicon elastomer, which comprises a cured dimethylsiloxane polymer and Hexsyn, having a composition of one-hexane with three to five percent methylhexaiene. A preformed elastomer may be inserted into the inclusion upon curing or, alternatively, as discussed with reference to Figure 12, may
10 be injected into the disc space and liquid form. Chemicals may be added to accelerate curing, as discussed above, or, a hot or cold probe, or UV light may be introduced to facilitate or accelerate the curing process. Preferably, such materials would include a radio-opaque additive which would enable the physician to verify the position of the implant with an X-ray. Ideally, the radio-opaque additive would not change the mechanical properties of
15 the gel or elastomer, and would ideally incorporate contrast throughout to enhance detail.

Now making to Figures 13 and 14, Figures 13A and 13B illustrate an alternative type of stent having leaves or other appendages that may be folded into a compact state for insertion, Figure 13A, and which expand, through memory affect, for example, to a state such as that shown in Figure 13B. A stent such as this, as well as other devices disclosed
20 herein such as the coil form of Figure 11, may be used in conjunction with a gel or other void-filling material as described above. As shown in Figure 14A, a stent 1402 of the type shown with respect to Figure 13B, may be introduced into the void, after which the

remaining volume of the void may be filled with a material 1404 which solidifies into a resilient material. Figure 14B is a side-view drawing of the embodiment of Figure 14A. An expandable stent of this kind may be incorporated into the elastomer or other resilient material to help prevent migration of the prosthesis through the annular hole. In contrast to
5 embodiments of the invention wherein a stent is used independently, in this particular embodiment, the stent would preferably not touch vertebra, since it would be surrounded entirely by the elastomer or other gel material.

Figures 15A-15E illustrate various alternative embodiments according to the invention wherein a patch material is used inside, outside, or partially inside and outside of a
10 defect to be blocked. Figure 15A illustrates a flat patch attached onto the outside of the disc. Figure 15B illustrates a patch attached on the outside but wherein a central portion extends inwardly into the void. Figure 15C illustrates a patch disposed within the disc to block the defect. Figure 15D illustrates how a patch may be anchored to the bone above and below the disc, and Figure 15E illustrates how the patch may be anchored to the disc itself. The patch
15 material be a fiber, including natural materials, whether human, non-human or synthetic; an elastomer; plastic; or metal. If a fiber material is used, it may be selected so as to promote tissue in-growth. Growth of a patient's tissue into the material would assure a more permanent closure of the annular window. The patch may be attached within appropriate means, including stitches, staples, glue, screws or other special anchors.

20 In addition to the use of patches attached with sutures, staples or other materials, the annular defect may be closed with staples or other devices which attach to the annulus without the need for patch material. For example, as shown in Figure 16A, darts 1602 may

be inserted through the wall of the annulus 1604, then linked with sutures 1606, preferably in woven or criss-crossed fashion, as shown in Figure 16B. As an alternative, appropriately shaped darts 1702 may be criss-crossed or otherwise interlocked to close the annular hole, as shown in the top-view cross-section drawing of Figure 17A or a side-view of Figure 5 17B.

The use of flexible stents as described elsewhere herein may take on other forms, as shown in Figures 18A-18D. The device of Figure 18A, for example, preferably includes a body 1802, preferably including a blunt anterior end to prevent penetration of the anterior annulus, and outer spikes 1806, preferably having different lengths, as best seen in the on- 10 axis view of Figure 18B. Such a stent configuration may provide more areas of contact with the vertebral end plates, thereby decreasing the chances of stent extrusion. As shown in Figure 18C, the longer spikes 1806 are configured to bend during insertion, thereby preventing posterior extrusion. The shorter spikes, 1806', are sized so as not to engage the vertebrae, and therefore may be made thicker to prevent deflection by disc material. As an 15 option, the shorter spikes 1806' may also be angled in the opposite direction as compared to the longer spikes 1806 to resist migration of the disc material. As yet a further option, the longer spikes may vary in length on the same stent so as to be conformal to the vertebral end plate concavity. As shown in Figure 18D, multiple spike stents of this kind may be inserted so as to interlock with one another, thereby preventing migration of the group.

20 As shown in Figures 19A-19C, shapes other than spiked stents may be used in interlocking fashion. In Figure 19A, a first piece 1902 is inserted having a removable handle 1904, after which pieces 1902' and 1902'' are inserted, each having their own removable

handles, as shown. In Figure 19B, the handles are pulled, so as to bring the pieces together, and in Figure 19C, the handles are removed, and the pieces are either snapped together or, through the use of suitable material, sutured into place. Figures 20A-20E illustrate a different configuration of this kind, wherein a body 2002 having anchor or wire-receiving apertures 2004 is inserted into the annular hole, as shown in Figure 20B, at which time a wire 2006 is inserted through the body 2002 as shown in Figure 20C. As shown in Figure 20D, the wire is installed sufficient to lock one portion of the body into place, and this is followed with a wire on the opposite side, thereby holding the body 2002 in a stabilized manner. It will be appreciated that although multiple wires or anchors are used in this configuration, bodies configured to receive more or fewer wires or anchors are also anticipated by this basic idea.

Figures 21A-21C illustrate a different alternative, wherein wires 2102 each having a stop 2104 are first inserted through the annular window, after which blocking beads having snap-in side configurations are journaled onto the wire across the annular hole, as shown in Figure 21B. Figure 21C illustrates how, having locked multiple beads onto the wire, the defect is affectively occluded. Figures 22A and 22B illustrate the use of a removable dam component. As shown in Figure 22A, bodies 2202, each having removable handles 2204, are first inserted on the side portions of the defect, each member 2202 including slots, grooves or apertures 2206, configured to receive a dam 2210, which may be made of a rigid or pliable material, depending upon vertebral position, the size of the defect, and other factors. Figure 22B illustrates the dam 2210 locked in position.

Certain of the following embodiments illustrate how the invention permits the use of

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a flexible device which allows movement between the vertebrae yet blocks extrusion of nucleus through an annular hole or defect. In Figure 23A, for example, a flexible element 2302 is tacked into position on the upper vertebrae, as perhaps best seen in Figure 23D, though it should be apparent that a fixation to the lower vertebrae may also be used. Figure 5 23B illustrates how, once the member 2302 is fastened in place, it may flex under compression, but return to a more elongated shape in distraction, as shown in Figure 23C. The blocking element 2302 may be made from various materials, including shape-memory materials, so long as it performs the function as described herein. Figure 24A illustrates a different configuration, which is tacked to both the upper and lower vertebrae, and Figures 10 24B and 24C show how the device performs in compression and distraction, respectively. Since devices attached to both the upper and lower vertebrae need not automatically assume a memorized shape, alternative materials may preferably be used, including biocompatible rubbers and other pliable membranes. It is important that the flexible member not be too redundant or stretched so as to compress the nerve, as shown in Figure 25. Figure 26 15 illustrates an alternative Z-shaped installation configuration.

As an alternative to inherently flexible materials which occlude a defect while accommodating compression and distraction, interleaving members may alternatively be used, as shown in Figures 27-28. Figure 27A is a view from an oblique perspective, showing how upper and lower plate 2702 and 2704 of any suitable shape, may be held together with 20 springs 2706, or other resilient material, between which there is supported interleaving tines 2708. As better seen in Figure 27B, the springs 2706 allow the upper and lower plates 2702 and 2704 to move toward and away from one another, but at all times, tines 2708 remain

interleaving, thereby serving to block a defect.

Figures 28A and 28B illustrate the way in which interleaving members or tines are preferably inserted directly to vertebrae. Since each member overlaps with the next, such tines are preferably installed from front to back (or back to front, as the case may be),
5 utilizing a tool such as 2810, as shown in Figure 28B. The instrument 2810 forces each tack into one vertebrae at a time by distracting against the other vertebrae, thereby applying pressure as the jaws are forced apart, driving the tack into the appropriate vertebrae. The tack may be held into place on the instrument by a friction fit, and may include a barbed end so as not to pull out following insertion.

10 As a further alternative configuration, a collapsed bag may be placed into the disc space, then filled with a gas, liquid or gel once in position. The bag may be empty, or may contain a stent or expanding shape to assist with formation. In the case of a gel, silicon may be introduced so as to polymerized or solidify. As shown in Figures 29A and 29B, the use of a non-contained silicon vessel may be used, but, under distraction, may remain in contact
15 with the vertebrae, thereby increasing the likelihood of a reaction to silicone. The invention therefore preferably utilizes a contain structure in the case of a silicon filler, as shown in Figure 30A, such that, upon distraction, the vessel remains essentially the same shape, thereby minimizing vertebral contact.

It is noted that, depending upon the configuration, that the invention may make use of
20 a bioabsorbable materials, that is, materials which dissolve in the body after a predetermined period of time. For example, if darts such as those shown in Figures 16 and 17 are used, they may bioabsorb following sufficient time for the in-growth of recipient tissue sufficient to

occlude the defect independently. Any of the other configurations described herein which might not require certain components in time may also take advantage of bioabsorbable materials. Furthermore, although the invention has been described in relation to preventing the release of natural disc materials, the invention may also be used to retain bone graft for
5 fusion; therapeutic materials including cultured disc cells, glycosaminoglycans, and so forth; and artificial disc replacement materials.

Disc fusions are generally performed for degenerative disc disease, spondylolysis (a stress fracture through the vertebra), spondylolisthesis (slippage of one vertebra on another), arthritis of the facet joints, spinal fractures, spinal tumors, recurrent disc herniations, and
10 spinal instability. The procedure attempts to eliminate motion between vertebra to decrease a patient's pain and/or prevent future problems at the intervertebral level.

Devices such as spinal cages are generally used in conjunction with such procedures to maintain the separation between the vertebrae until fusion occurs. Some surgeons believe that cages are not necessary to maintain the separation, and instead use pedicle screws or
15 hooks and rods to perform this function. Whether or not a cage is used, bone graft is generally introduced through a hole formed in the disc space to achieve an interbody fusion.

Unfortunately, bone material placed into the disc space can extrude through the hole used for insertion. Bone graft extruded through a hole in the posterior portion of the disc may cause nerve root impingement. The procedure to fuse vertebra across the disc space
20 from a posterior approach is known as a PLIF (posterior lumbar interbody fusion). Bone can also be placed into the disc space from an anterior approach ALIF (anterior lumbar interbody

fusion). Extruded bone from an anterior approach would not lead to nerve impingement but could decrease the likelihood of a successful fusion by decreasing the volume of bone graft.

The present invention may be used to prevent the loss of the bone graft material associated with fusion techniques, whether or not a cage is used. In this particular regard, however, some of the devices disclosed herein may be more suitable than others. Generally speaking, since the goal is not to preserve disc function and motion, the stent, plug, and patch embodiments may be more appropriate. Although the plug embodiment would be a good choice when there is ample room in the spinal canal to allow insertion, the expandable stent design would be beneficial when plug insertion risks nerve injury. Conversely, since the goal is to maximize the amount of bone inserted into the disc space, the embodiments using hydrogels and elastomers might not be optimum, since such materials may occupy too much space in some circumstances.

The preferred choice of materials may also be changed since motion is not being maintained. Materials and designs with shape memory may be beneficial. As another example, the polymer plug embodiment may be changed to a metal such as titanium. A metal plug may be fabricated with threads and screwed into place, as shown in Figure 31A, or the device may feature ridges and be impacted into place (Figure 31B). As shown in Figure 31C, the ridges may also be asymmetric to resist posterior migration. In all cases, the teeth, screw threads or ridges would extend at least partially into the adjacent vertebra for secure purchase, as depicted in Figure 31D. Such plugs may also be positioned bilaterally, that is, with two per level, as shown in Figure 32.

I claim:

1. Apparatus for preventing the escape of natural, artificial, or therapeutic
2 material through a defect in the annulus fibrosis of a spinal disc, comprising:
a device having a first physical extent facilitating introduction of the device relative
4 to a defect in an annulus fibrosis, and
a second physical extent, different from the first, wherein the device functions to
6 occlude the defect.

2. The apparatus of claim 1, wherein:
2 the device is composed of flexible or compressible material;
the first physical extent is achieved by compacting the device; and
4 the second physical extent is achieved through expansion of the device.

3. The apparatus of claim 2, wherein the device includes a flexible screen or
2 patch.

4. The apparatus of claim 1, further including one or more anchors to hold the
2 device in place relative to the defect.

5. The apparatus of claim 1, wherein:
2 the device is provided as a liquid or gel which solidifies to achieve the second
physical extent.

6. The apparatus of claim 5, including a hydrogel or elastomer.

7. The apparatus of claim 1, wherein:

2 the device is composed of material that naturally returns to a predetermined shape;
the first physical extent is achieved by straightening the device for introduction; and
4 the second physical extent is achieved as the device returns to the predetermined
shape.

8. The apparatus of claim 1, including a plurality of devices which function
2 collectively to achieve the second physical extent.

9. The apparatus of claim 8, wherein the devices are introduced separately.

10. The apparatus of claim 1, wherein the device occludes the defect while
2 allowing compression and distraction of the disc with respect to normal spinal movement.

11. The apparatus of claim 1, wherein the device incorporates a radio-opaque
2 contrast material.

12. A method of preventing the escape of natural, artificial, or therapeutic
2 material through a defect in the annulus fibrosis of a spinal disc, comprising the steps of:
inserting a device relative to a defect in an annulus fibrosis; and

- 4 occluding the defect by:
- 6 a) allowing the device to expand to a larger size,
 - 6 b) allowing the device to return to a memorized shape,
 - c) allowing the device to solidify, or
 - 8 d) by adding additional devices which physically cooperate following
installation.

10

13. The method of claim 12, wherein:

- 2 the step of inserting device includes compacting the device into a compressed form
for introduction relative to the defect.

14. The method of claim 12, wherein the device includes a flexible screen or
2 patch.

15. The method of claim 12, further including the step of anchoring each device
2 in place relative to the defect.

16. The method of claim 12, wherein the device includes a liquid or gel
2 which solidifies following injection into the defective area.

17. The method of claim 16, including a hydrogel or elastomer.

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18. The method of claim 12, wherein the device occludes the defect while
- 2 allowing compression and distraction of the disc with respect to normal spinal movement.

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Abstract of the Disclosure

Methods and apparatus for treating disc herniation provide a conformable device which assumes a first shape associated with insertion and a second shape or expanded shape to occlude the defect which typically follows partial discectomy. The device may take
5 different forms according to the invention, including patches size to cover the defect or plugs adapted to fill the defect. In a preferred embodiment, however, the device is a gel or other liquid or semi-liquid which solidifies to occlude the defect from within the body of the disc itself. In another preferred embodiment, a mesh screen is collapsed into an elongated form for the purposes of insertion, thereby minimizing the size of the requisite incision while
10 avoiding delicate surrounding nerves. Such a configuration also permits the use of instrumentation to install the device, including, for example, a hollow tube or sheath adapted to hold the collapsed screen, and a push rod to expel the collapsed device out of the sheath for use in occluding the disc defect. A device according to the invention may further include one or more anchors to assist in permanently affixing the device with respect to the defect.

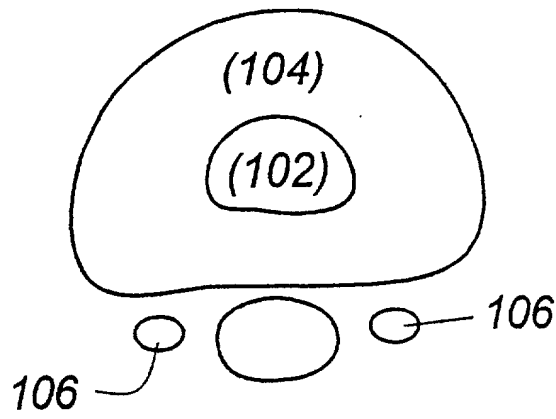


Figure - 1A

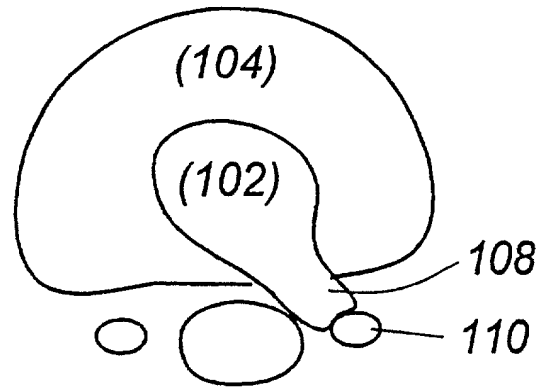


Figure - 1B

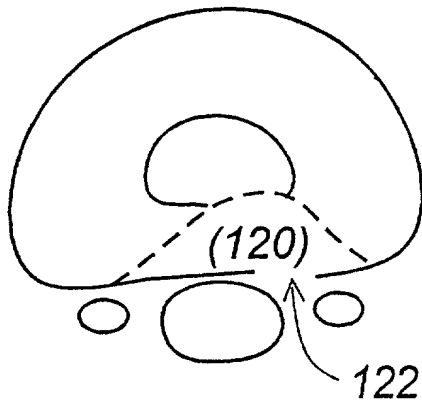


Figure - 1C

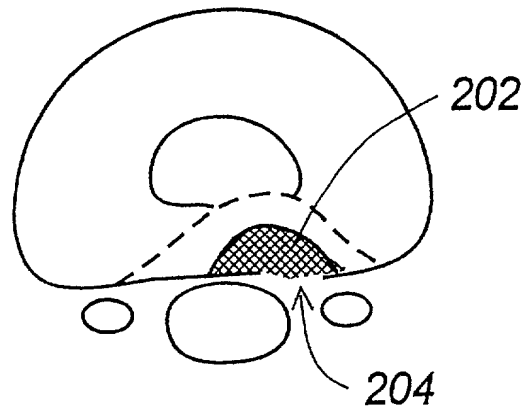


Figure - 2

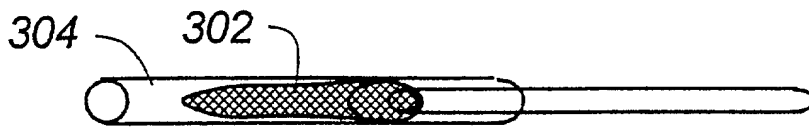


Figure - 3A

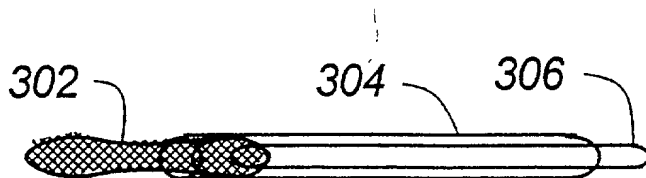


Figure - 3B

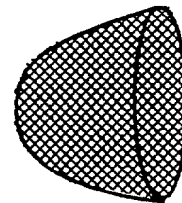


Figure - 3C

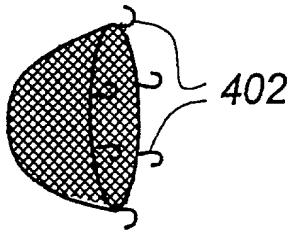


Figure - 4A

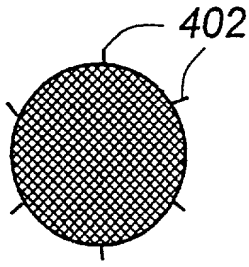


Figure - 4B

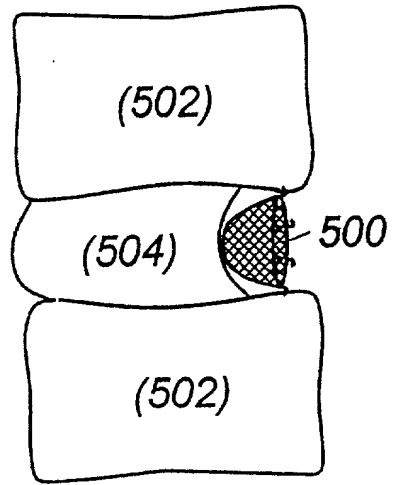


Figure - 5

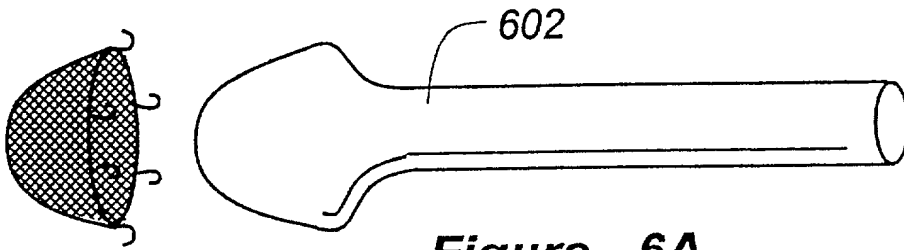


Figure - 6A

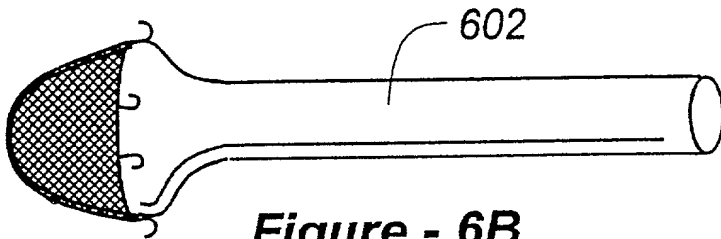


Figure - 6B

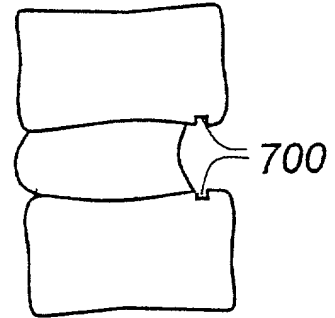


Figure - 7A

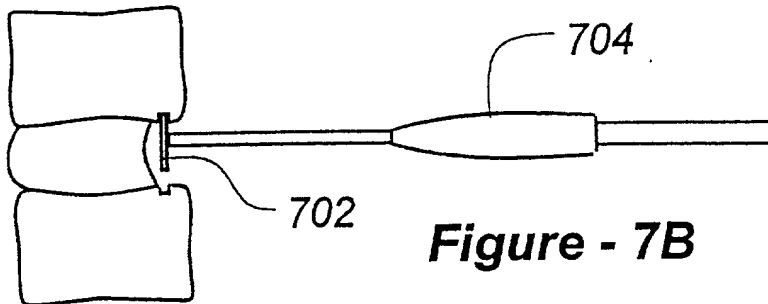


Figure - 7B

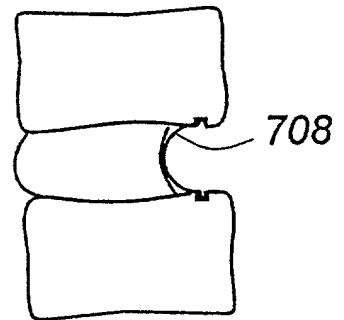


Figure - 7C

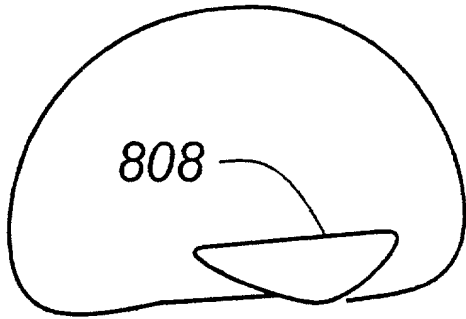


Figure - 8

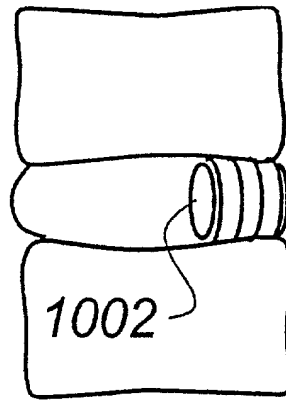


Figure - 10

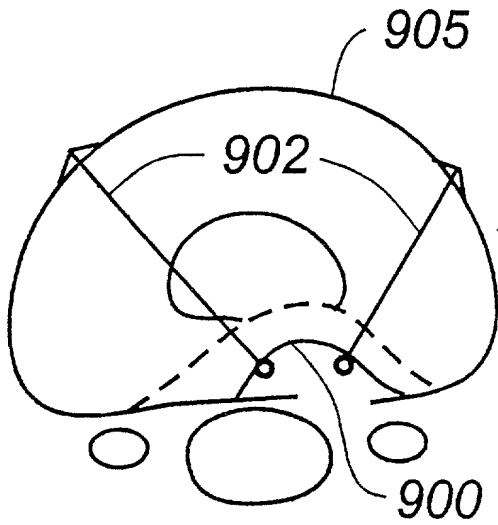


Figure - 9A

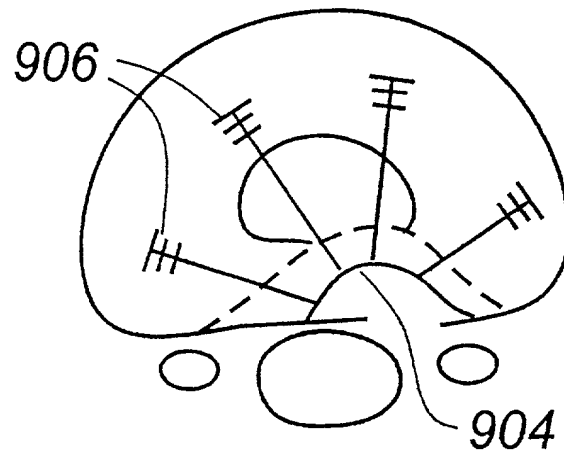


Figure - 9B

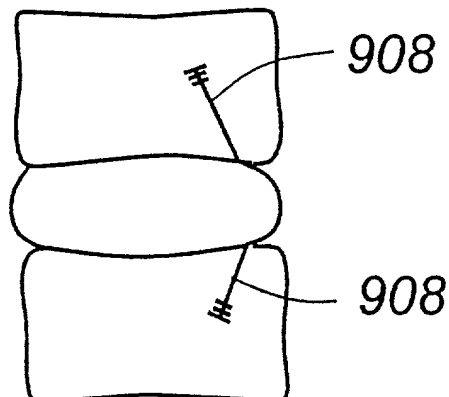


Figure - 9C

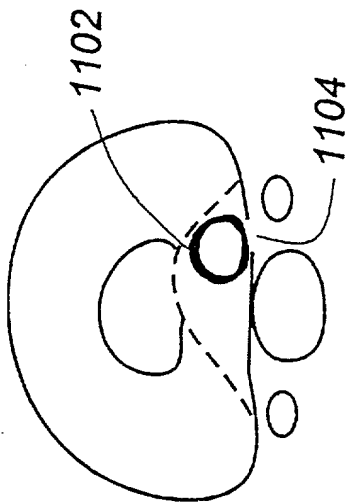


Figure - 11A

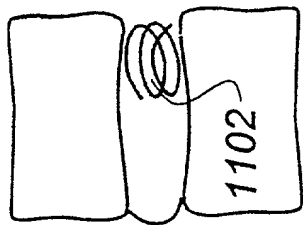


Figure - 11B

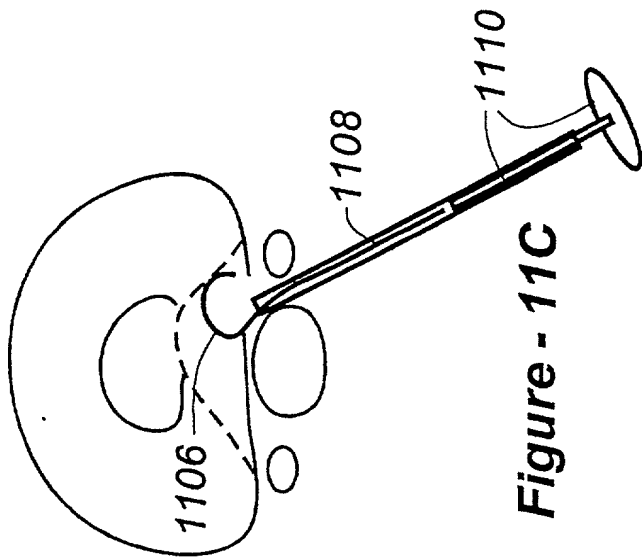


Figure - 11C

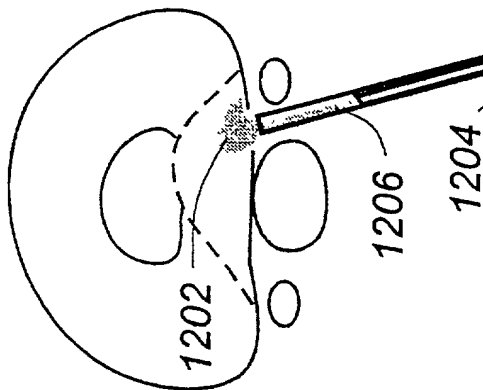


Figure - 12

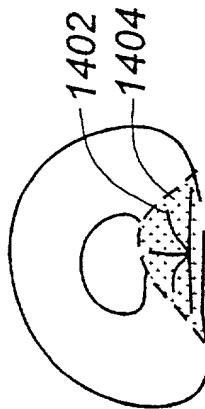


Figure - 14A

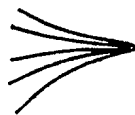


Figure - 13A

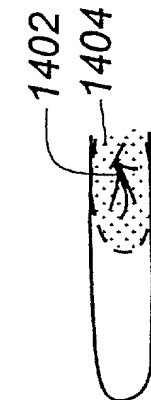


Figure - 14B



Figure - 13B

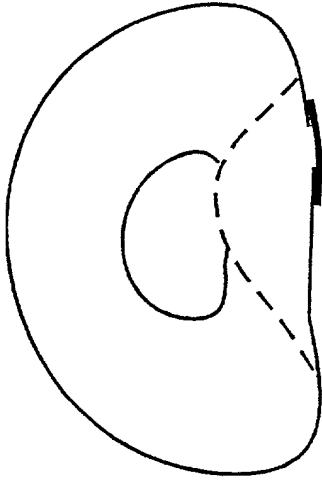


Figure - 15A

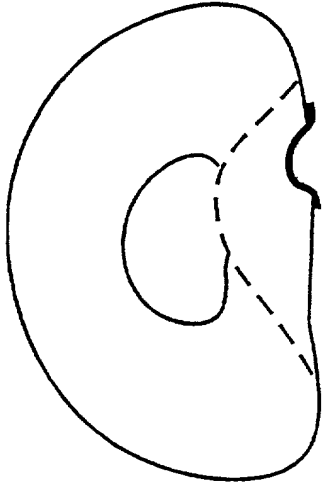


Figure - 15B

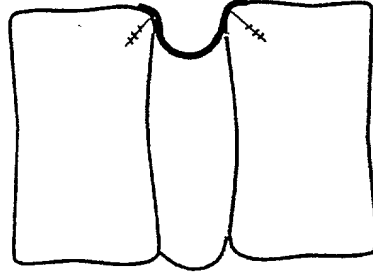


Figure - 15D

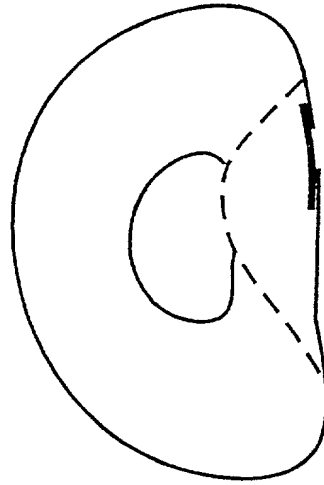


Figure - 15C

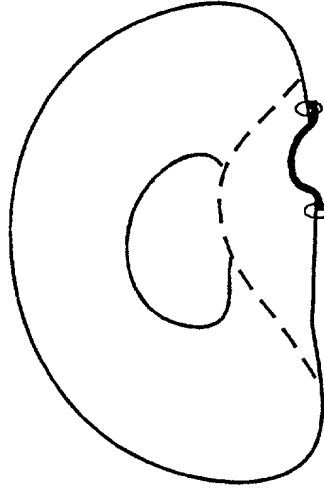


Figure - 15E

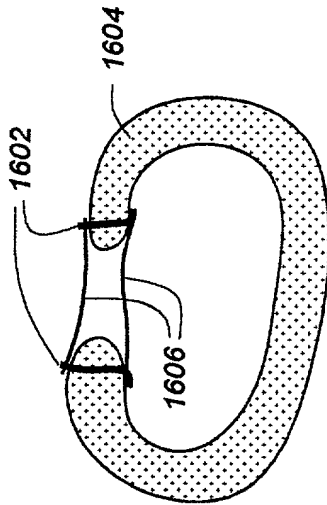


Fig - 16A

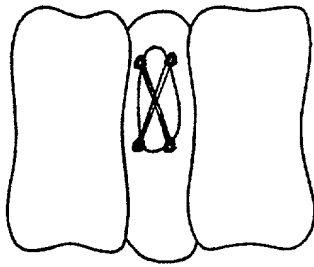


Fig - 16B

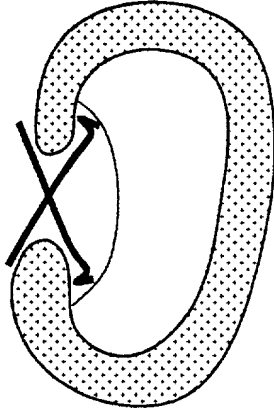


Fig - 17A

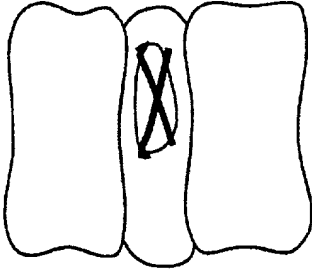


Fig - 17B

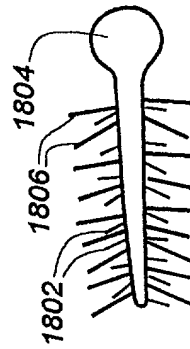


Fig - 18A

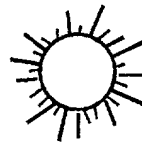


Fig - 18B

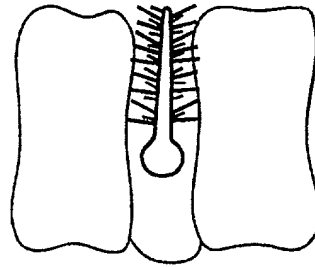


Fig - 18C

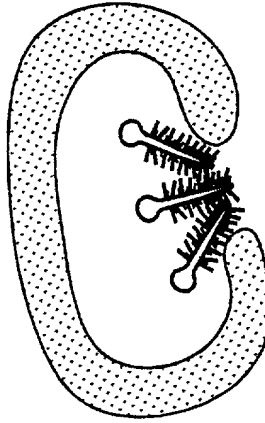


Fig - 18D

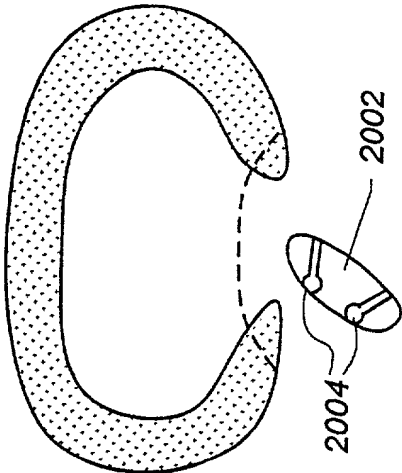


Fig - 20A

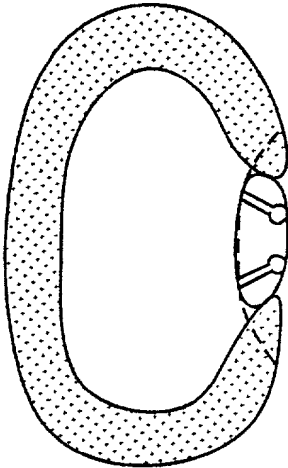


Fig - 20B

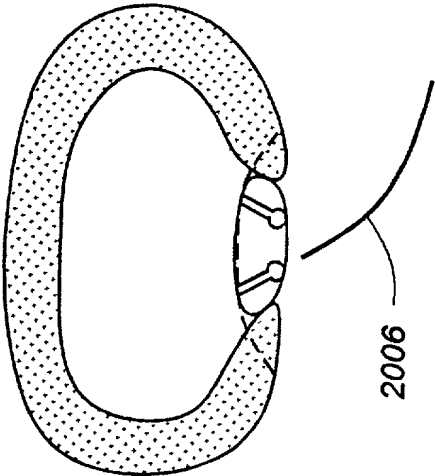


Fig - 20C

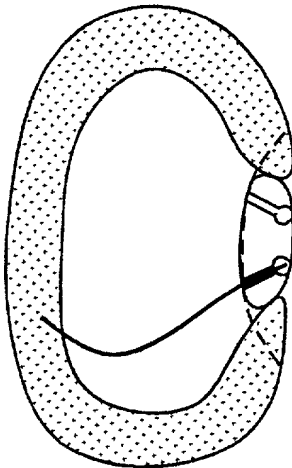


Fig - 20D

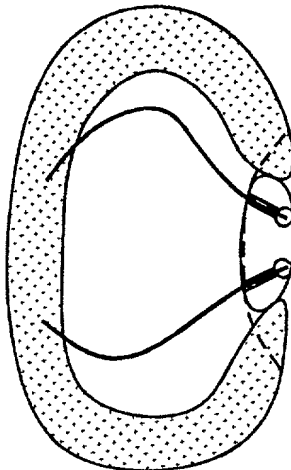


Fig - 20E

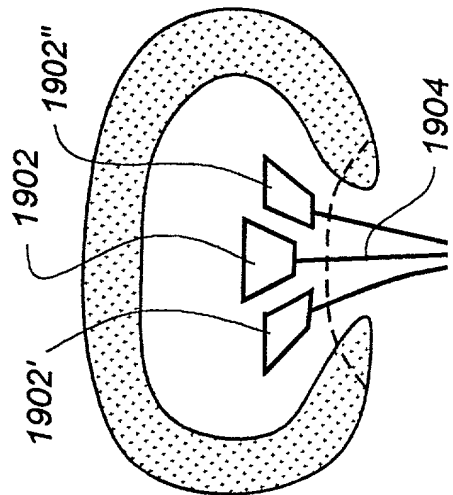


Fig - 19A

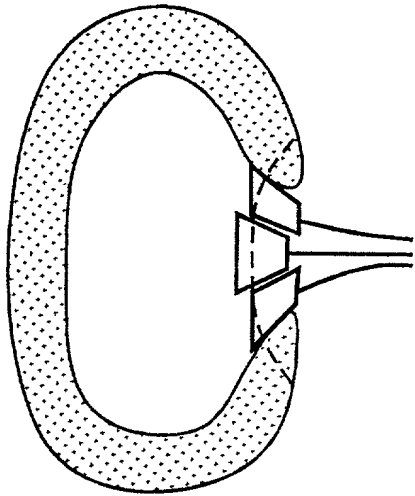


Fig - 19B

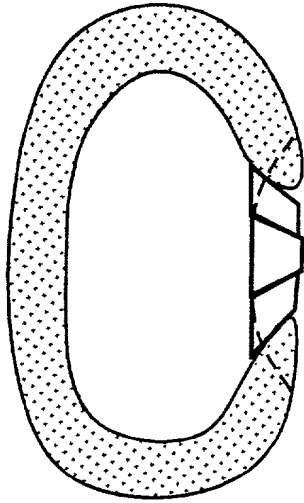


Fig - 19C

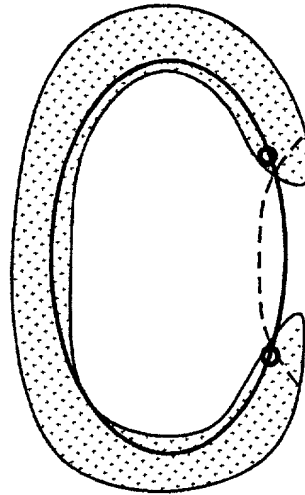


Fig - 21A

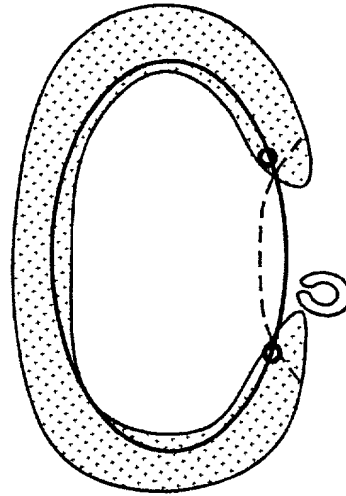


Fig - 21B

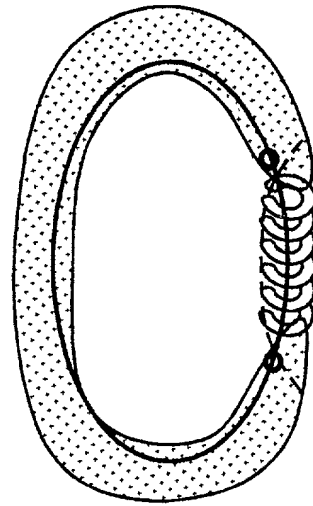


Fig - 21C

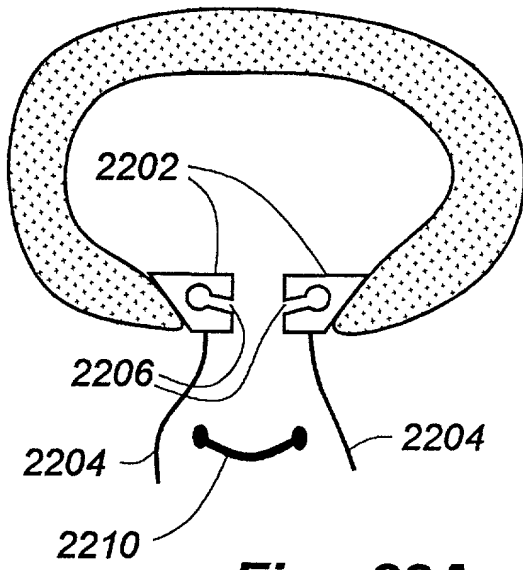


Fig - 22A

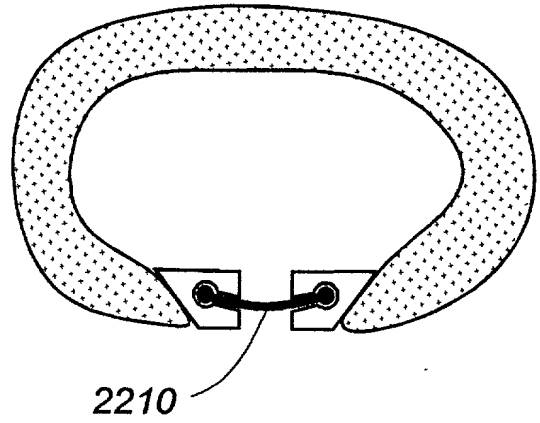


Fig - 22B

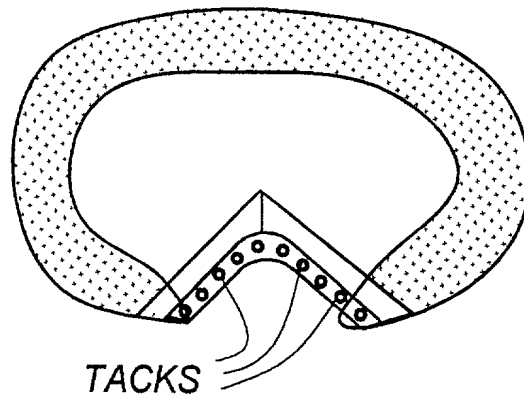


Fig - 23D

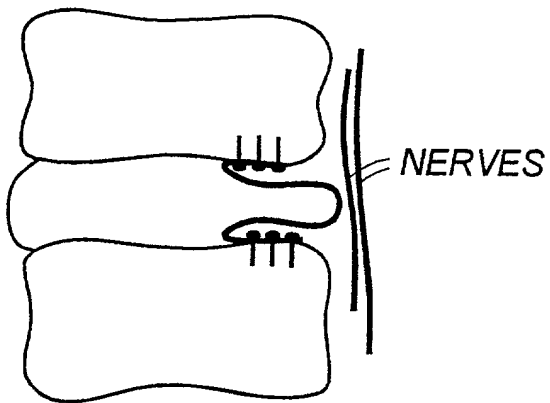


Fig - 25

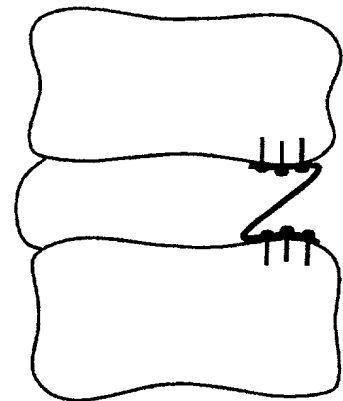


Fig - 26

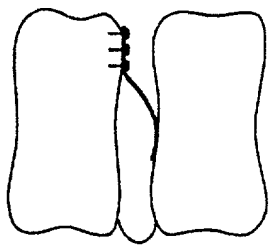


Fig - 23B

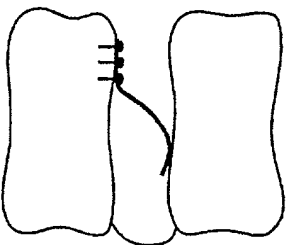


Fig - 23A

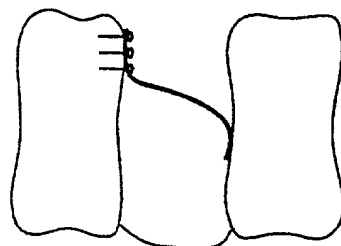


Fig - 23C

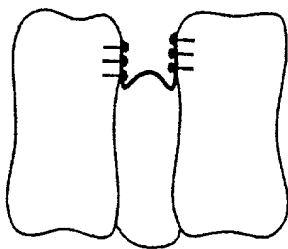
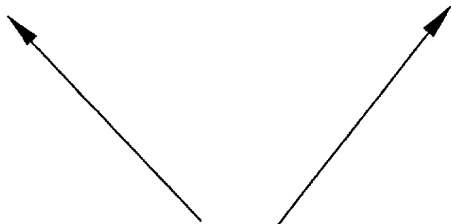


Fig - 24A

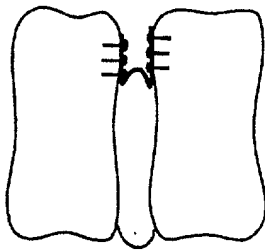


Fig - 24B

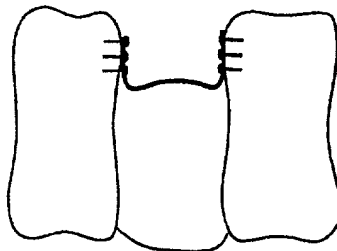
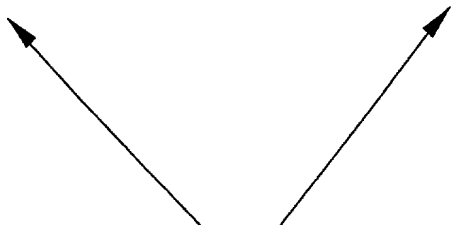


Fig - 24C



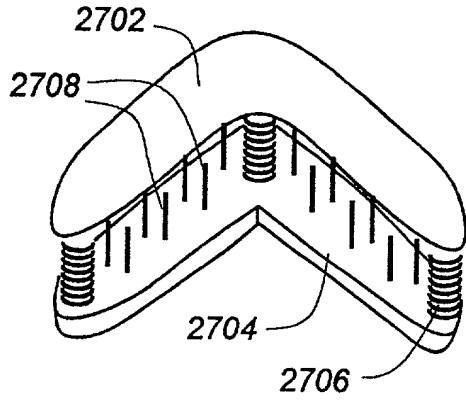


Fig - 27A

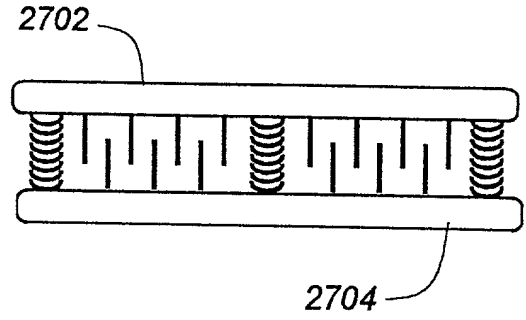


Fig - 27B

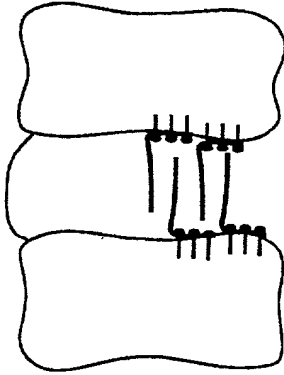


Fig - 28A

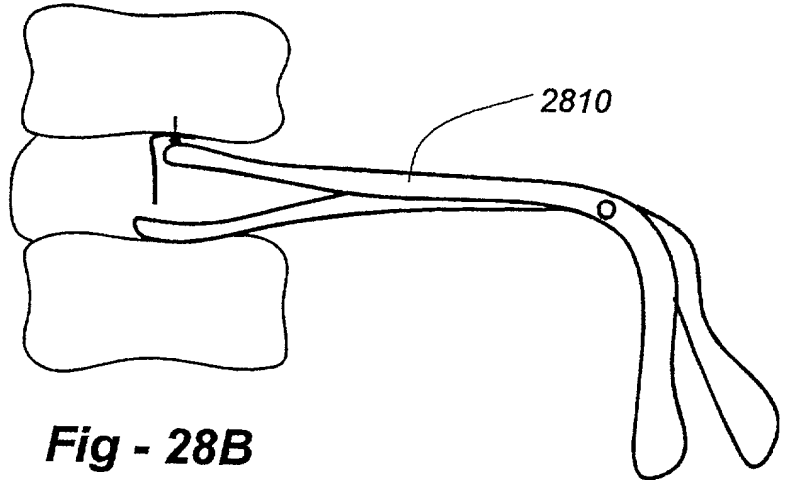


Fig - 28B

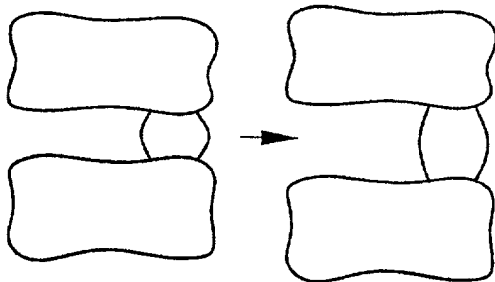


Fig - 29A

Fig - 29B
(DISTRACTION)

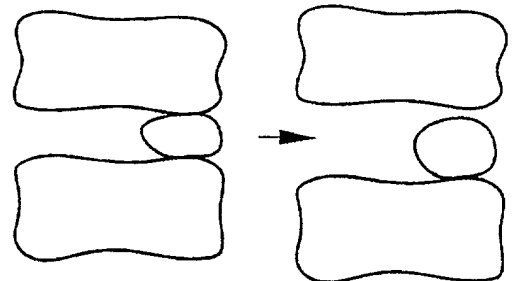
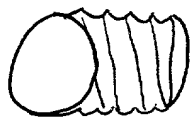


Fig - 30A

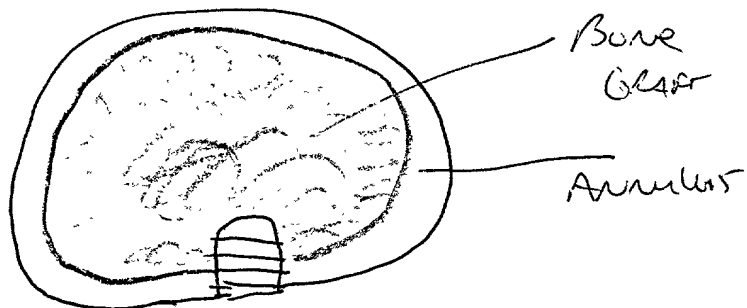
Fig - 30B
(DISTRACTION)

Types of PLUGS 1002

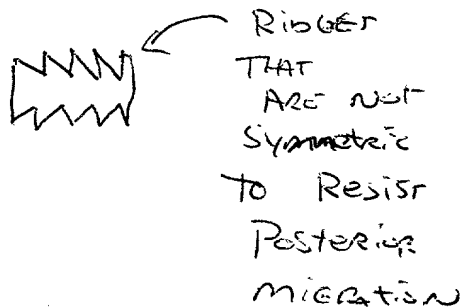
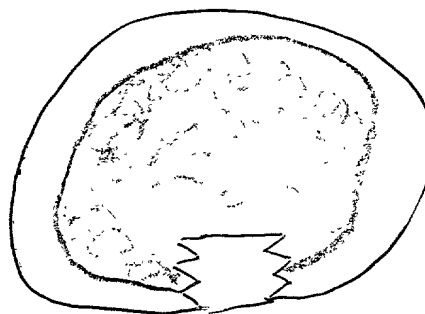
6



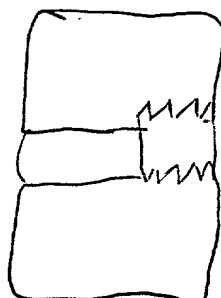
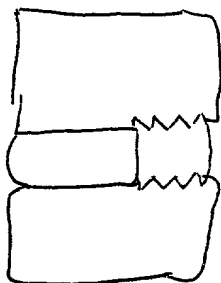
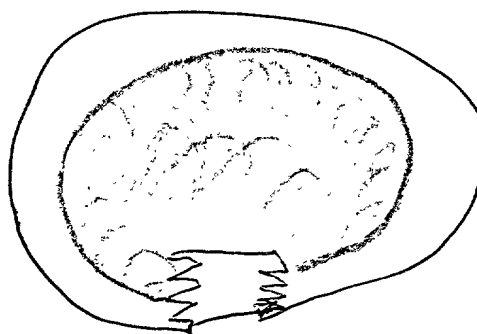
THREADED
TO SCREW INTO
PLACE



← RIDGES
TO
IMPACT
INTO
PLACE



← RIDGES
THAT
ARE NOT
SYMMETRIC
TO RESIST
POSTERIOR
MIGRATION



TEETH AND
SCREW
THREADS
ARE INTO
VERTEBRA
FOR SECURE
PURCHASE

PLUGS MAY BE PLACED
BILATERALLY (2/LEVEL)

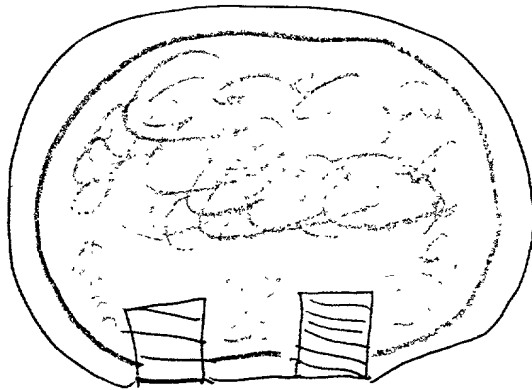
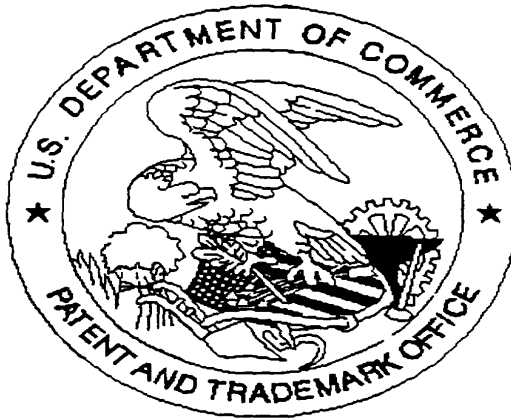


Fig 32

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